

REMARKS

Upon entry of present amendments, claims 1, 2, 5-10, 17, 18, 20-24, 26, 27, 43, and 97-132 will be pending. Claims 3, 8, 19, and 48-96 have been cancelled by the present amendment. New claims 97-132 have been added. Claims 2, 6, 7, 10, 17, 18, 20-24, 26, and 97-132 are currently under examination. Claims 2 and 22 have been amended without prejudice to further prosecution. Claim 2 has been amended to remove certain recited compounds. Support for amended claim 2 can be found throughout the specification as filed, e.g., at page 3, lines 24-25, and at page 15, lines 23-24. Claim 22 has been amended to correct antecedent bases and grammatical formalities.

Support for new claims 97-132 can be found throughout the specification as filed. For example, support for claims 97 and 123 can be found in the specification at page 18, lines 29-31 through page 19, lines 1-2, at page 19, lines 7-8, 10-11, and 17, and at page 20, lines 1-2. Support for claims 98, 104, 124, and 130 can be found, e.g., in the specification at page 20, lines 6-13. Support for claims 99 and 125 can be found, e.g., in the specification at page 17, lines 24-27. Support for claims 100-103 and 126-129 can be found in the specification, e.g., at page 18, lines 8-13. Support for claims 105 and 131 can be found in the specification, e.g., at page 18, lines 18-19. Support for claims 106 and 132 can be found in the specification at page 16, lines 7-17. Support for claims 107 and 108 can be found in the specification at page 15, lines 1-5 and 23-24. Support for claims 109-122 can be found, e.g., at page 18, lines 28-31 through page 19, lines 1-22. Applicants submit that no prohibited new matter has been added.

Information Disclosure Statements

Applicants note with appreciation that the Examiner has considered the references listed with the Information Disclosure Statement (IDS) forms mailed on November 5, 2007, and on January 9,

2008. Applicants also note with appreciation that the Examiner has considered the U.S. Patent Documents and Other Documents listed on the IDS form mailed on July 9, 2008. However, the seventeen Foreign Patent Documents listed on the IDS form mailed on July 9, 2008, have not been considered by the Examiner. Applicants respectfully request the consideration of these Foreign Patent Documents.

For Foreign Patent Documents JP 2004532889 T2, JP 2005524652 T2, and MX 3011082 A, the Examiner indicated that the documents were not considered because the documents are not in English. Applicants submit that English language translations of the abstracts of these three foreign patents were included with the submissions, along with the explanation that these foreign patents were family members of various US Patent Documents cited on the same IDS. For consideration by the Examiner, 37 C.F.R. 1.98 (a)(3)(i) requires that Applicant provide "[a] concise explanation of the relevance, as it is presently understood . . . of each patent, publication, or other information listed that is not in the English language" and 37 C.F.R. 1.98 (a)(3)(ii) requires that Applicant provide "[a] copy of the translation if a written English-language translation of a non-English-language document, or portion thereof, is within the possession, custody, or control of, or is readily available." Applicants submit they have fulfilled the requirements of 37 C.F.R. 1.98 and the consideration of these three documents by the Examiner is respectfully requested.

For the remaining fourteen Foreign Patent Documents, the Examiner indicated that the documents were not considered, as no copies of these documents were provided. Applicants respectfully submit that this is incorrect, as evidenced by the accessibility of all seventeen foreign patent documents included with the IDS filed July 9, 2008, in Image File Wrapper of the U.S. Patent and Trademark Office's PAIR database. Applicants respectfully request the consideration of these Foreign Patent Documents.

Rejections under 35 U.S.C. § 102(b)

The Examiner has rejected claims 2, 3, 6, 8, and 17-19 as allegedly being anticipated by Van Den Eynde *et al.*, WO 00/66764 (Van Den Eynde) (Office Action at pages 6-7). Without agreeing with the rejection, Applicants respectfully submit that the amendments to claim 2 render the present rejection moot. Claim 2, as amended, recites a method that includes administering an effective amount of a pharmaceutical composition *consisting essentially of* 1-methyl-D-tryptophan. Because Van Den Eynde does not teach administering a composition *consisting essentially of* 1-methyl-D-tryptophan, it does not anticipate the pending claims. Therefore, withdrawal of the present anticipation rejection is respectfully requested. Applicants respectfully submit that this rejection is also not applicable to new claims 97-132. Claims 97-106 depend from claim 2. Claims 107-132 recite the use of a pharmaceutical composition comprising: (a) 1-methyl-D-tryptophan *but not 1-methyl-(D,L)-tryptophan* or (b) 1-methyl-D-tryptophan *but not 1-methyl-L-tryptophan*, and therefore are not anticipated by Van Den Eynde.

Double Patenting

The Examiner has also provisionally rejected claims 6-10, 17-42, and 26 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4-7, 9-13, 30, 31, 33, and 36 of copending U.S. application serial number 10/780,797 (at page 7). Applicants respectfully request that the double patenting rejection be held in abeyance until the application is otherwise in condition for allowance, at which time Applicants will consider whether submission of a terminal disclaimer is appropriate.

Rejections under 35 U.S.C. § 112, First Paragraph - Enablement

The Examiner rejected claims 2, 3, 6-10, 17-24, and 26 as allegedly being not enabled by the specification (Office Action at pages 7-9). Without conceding to the substance of the rejection, but solely to expedite allowance, Applicants amended the claims to recite

administering an effective amount of a pharmaceutical composition consisting essentially of *1-methyl-D-tryptophan* (independent claim 2). In addition, new claims that are directed to administering an effective amount of a pharmaceutical composition comprising: (a) *1-methyl-D-tryptophan* but not 1-methyl-(D,L)-tryptophan (independent claim 107) or (b) *1-methyl-D-tryptophan* but not 1-methyl-L-tryptophan (independent claim 108) have been submitted. The scope of the claims as amended is fully supported and enabled by the specification.

The Examiner has acknowledged that treatment of melanoma with 1-methyl-tryptophan and cyclophosphamide is enabled, however, the Examiner questions enablement of *non-melanoma* cancer types with 1-methyl-tryptophan and *other* cancer therapeutics. In this regard, Applicants show a synergistic effect of 1-methyl-D-tryptophan (D-1MT) in an *in vivo* cancer model with *both* radiation and chemotherapeutic agents (see pages 52-53 of the specification). Given these results, and the fact that radiation and chemotherapy act by different mechanisms in cancer treatment, one of skill in the art would fully expect D-1MT to find use in a wide array of cancer treatment regimens in conjunction with a wide array of different therapies.

Further, Applicants submit herewith Declaration of Dr. George C. Prendergast, which includes data showing that administration of D-1MT as part of a treatment regimen also including administration of a chemotherapeutic agent resulted in the inhibition of two other types of tumor cells: *lung* cancer cells and *colon* cancer cells. Therefore, one skilled in the art would be able to utilize the present invention in a wide variety of cancers, as the methods of the present invention have broad applicability.

For the reasons presented above, withdrawal of all nonenablement rejections is respectfully requested.

Objections

The Examiner objected to claim 2 (page 9 of the Office Action) as reciting the "inhibitor or indoleamine-2,3-dioxygenase." Claim 2 has been amended to remove this phrase, rendering the objection moot. Therefore, withdrawal of this objection to claim 2 is respectfully requested.

Rejections under 35 U.S.C. § 112, Second Paragraph

Claim 3 was rejected as allegedly being indefinite (at page 10 of the Office Action).
Claim 3 has been cancelled by the present amendment, rendering the rejection moot.

Claim 22 was rejected as allegedly being indefinite for reciting the phrase "the tumor is a melanoma vaccine" (at page 10). Claim 22 depends from claim 21, which recites a tumor vaccine. Claim 22 has been amended to reflect correct antecedent bases and grammatical formalities, *i.e.*, to clarify that the tumor vaccine is a melanoma vaccine.

At least for the reasons presented above, withdrawal of all indefiniteness rejections is respectfully requested.

Rejections under 35 U.S.C. § 112, First Paragraph – Written Description

Claims 2-3, 6-10, 17-24, and 26 were rejected as allegedly failing to comply with the written description requirement (at pages 11-12).

According to the Examiner, "[t]he introduction of the limitation 'an isolated' D isomer of the elected compound in claim 2 does not have a written basis in the application as filed" (at page 11). Without conceding to the substance of the rejection, Applicants amended claim 2, which no longer uses the word "isolated." Rejection of claim 2 and its dependent claims 6-10, 17-24, and 26 is therefore rendered moot. Claim 3 has been cancelled.

The Office further states that "[t]he introduction of the phrase 'the tumor is a melanoma vaccine' in claim 22 changes the meaning of 'the tumor vaccine is a melanoma vaccine' presented

in the previous claim set" (at page 11). Claim 22 has been amended accordingly, rendering the rejection moot.

For the reasons presented above, withdrawal of all written description rejections is respectfully requested.

Applicants note with appreciation that the Examiner withdrew previous written description rejections (at page 9).

SUMMARY

Applicants respectfully submit that the claims are now in condition for allowance, early notice of which would be appreciated. Should the Examiner disagree, Applicants respectfully request a telephonic or in-person interview with the undersigned attorney to discuss any remaining issues and to expedite the eventual allowance of the claims.

The Examiner is invited to contact Applicants' Representatives at the telephone number listed below if they can be of any assistance during prosecution of the present application.

CERTIFICATE UNDER 37 C.F.R.1.8:
<p>The undersigned hereby certifies that this paper is being transmitted via the U.S. Patent and Trademark Office electronic filing system in accordance with 37 CFR §1.6(a)(4) to the Patent and Trademark Office addressed to: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.</p> <p>on this <u>14</u> day of <u>October</u>, 2008.</p> <p>By: <u>Sandy Truhart</u></p> <p>Name: <u>Sandy Truhart</u></p>

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